4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0039]

Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing the availability of version 2.2 of the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports (ICSRS) for Vaccines (Specifications). The version update is not applicable to CBER-regulated drug products marketed for human use with approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs); CBER-regulated therapeutic biological products marketed for human use with approved Biologic License Applications (BLAs); Whole Blood or blood components; and human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under the Public Health Service Act.

ADDRESSES: You may submit either electronic or written comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's

Social Security Number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0039 for "Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification". Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that

states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

CBER is announcing the availability of version 2.2 of the Specifications for Preparing and Submitting Postmarket ICSRs for Vaccines (available at https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation). The version update

has been prepared to accommodate the submission of certain reports for combination products required by an FDA rule, "Postmarketing Safety Reporting for Combination Products", published in the *Federal Register* of December 20, 2016 (81 FR 92603) (available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products). In addition, version 2.2 includes updated business rules (Appendix I of the Specifications) which provide details on data field specifications as well as updated sample Extensible Markup Language (XML) ICSR test files (available at https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation). The version update is not applicable to CBER-regulated drug products marketed for human use with approved NDAs and ANDAs; CBER-regulated therapeutic biological products marketed for human use with approved BLAs); Whole Blood or blood components; and HCT/Ps regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264).

Vaccine manufacturers and others responsible for reporting ICSRs for vaccines can now transition to reporting in the updated version 2.2. Instructions to transition are available at https://www.fda.gov/vaccines-blood-biologics/getting-started-icsr-submission-fdas-electronic-vaccine-adverse-event-reporting-system-evaers. Manufacturers can contact the CBER ICSR Submissions Coordinator (CBERICSRSubmissions@fda.hhs.gov) to inform of their intent to transition to version 2.2 of the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines. Although manufacturers are encouraged to transition to the updated version 2.2, CBER continues to accept reports in version 1.0 until further notice.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy

[FR Doc. 2021-07332 Filed: 4/8/2021 8:45 am; Publication Date: 4/9/2021]